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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,641	09/15/2003	David Standring	06171.105097 (IDX 1021 US	2664

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KING & SPALDING LLP
191 PEACHTREE STREET, N.E.
45TH FLOOR
ATLANTA, GA 30303-1763

EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,641	STANDRING ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-75 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 5 in part, 6-25, and 74-75, drawn to methods of treating a host infected with a drug-resistant form of HBV that exhibits a mutation at the 552 codon in the DNA polymerase region by administering a β-L-2'-deoxynucleoside (i.e, where X of formula I of claim 5 is O or S), classified in class 514, subclass 42+.

II. Claims 5 in part and 74-75, drawn to methods of treating a host infected with a drug-resistant form of HBV that exhibits a mutation at the 552 codon in the DNA polymerase region by administering a β-L-2'-deoxynucleoside where X of formula I is SO_2, classified in class 514, subclass 183+.

III. Claims 5 in part and 74-75, drawn to methods of treating a host infected with a drug-resistant form of HBV that exhibits a mutation at the 552 codon in the DNA polymerase region by administering a β-L-2'-deoxynucleoside where X of formula I is CH_2, classified in class 514, subclass 183+.

IV. Claims 26, 27 in part, and 28-47, drawn to methods for preventing or suppressing the expression of a mutation at the 552 codon in the DNA polymerase region of HBV by administering a β-L-2'-deoxynucleoside (i.e., where X of formula I of claim 30 is O or S), classified in class 514, subclass 42+.

V. Claim 27 in part, drawn to methods for preventing or suppressing the expression of a mutation at the 552 codon in the DNA polymerase region of HBV by administering a β-L-2'-deoxynucleoside where X of formula I is SO_2, classified in class 514, subclass 183+.

VI. Claim 27 in part, drawn to methods for preventing or suppressing the expression of a mutation at the 552 codon in the DNA polymerase region of HBV by administering a β-L-2'-deoxynucleoside where X of formula I is CH_2, classified in class 514, subclass 183+.

VII. Claims 48, 49 in part, and 50-69, drawn to methods for preventing or suppressing the expression of a mutation at the 552 codon and at either the 526 or 528 codon in the DNA polymerase region of HBV by administering a β-L-2'-deoxynucleoside (i.e., where X of formula I of claim 49 is O or S), classified in class 514, subclass 42+.

VIII. Claim 49 in part, drawn to drawn to methods for preventing or suppressing the expression of a mutation at the 552 codon and at either the 526 or 528 codon in the DNA polymerase region of HBV by administering a β-L-2'-deoxynucleoside, where X of formula I is SO_2, classified in class 514, subclass 183+.

IX. Claim 49 in part, drawn to drawn to methods for preventing or suppressing the expression of a mutation at the 552 codon and at either the 526 or 528 codon in the DNA polymerase region of HBV by administering a β-L-2'-deoxynucleoside, where X of formula I is CH_2, classified in class 514, subclass 183+.

X. Claims 70-73 in part, drawn to methods of group I further comprising additionally administering one or more other anti-HBV agents, classified in class 514, subclass 42+.

XI. Claims 70-73 in part, drawn to methods of group II further comprising additionally administering one or more other anti-HBV agents, classified in class 514, subclass 183+.

XII. Claims 70-73 in part, drawn to methods of group III further comprising additionally administering one or more other anti-HBV agents, classified in class 514, subclass 183+.

XIII. Claims 70-73 in part, drawn to methods of group IV further comprising additionally administering one or more other anti-HBV agents, classified in class 514, subclass 42+.

XIV. Claims 70-73 in part, drawn to methods of group V further comprising additionally administering one or more other anti-HBV agents, classified in class 514, subclass 183+.

XV. Claims 70-73 in part, drawn to methods of group VI further comprising additionally administering one or more other anti-HBV agents, classified in class 514, subclass 183+.

XVI. Claims 70-73 in part, drawn to methods of group VII further comprising additionally administering one or more other anti-HBV agents, classified in class 514, subclass 42+.

XVII. Claims 70-73 in part, drawn to methods of group VIII further comprising additionally administering one or more other anti-HBV agents, classified in class 514, subclass 183+.

XVIII. Claims 70-73 in part, drawn to methods of group IX further comprising additionally administering one or more other anti-HBV agents, classified in class 514, subclass 183+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and III are unrelated. It is noted that the invention of group I is drawn to treating a host infected with a drug resistant form of HBV which exhibits a mutation at the 552 codon in the DNA polymerase region by administering a nucleoside. Groups II and III are drawn to the same method, but they use divergent and patentably distinct compounds in their methods. Group I uses nucleosides or compounds where X of formula I is O or S. Group II uses compounds which have SO_2 in the X position and group III uses compounds which have CH_2 in the X position. As such, a search for a method of group I would not be required for a search for the methods of groups II and III, and a reference anticipating or rendering one group obvious would not necessarily anticipate or render the other groups obvious.

Inventions IV, V, and VI are unrelated. It is noted that the invention of group IV is drawn to preventing or suppressing the expression of a mutation at the 552 codon in the DNA polymerase region of HBV in a host by administering a nucleoside. Groups V and VI are drawn to the same method, but they use divergent and patentably distinct compounds in their methods. Group IV uses nucleosides or compounds where X of formula I is O or S. Group V uses compounds which have SO_2 in the X position and group VI uses compounds which have CH_2 in

the X position. As such, a search for a method of group IV would not be required for a search for the methods of groups V and VI, and a reference anticipating or rendering one group obvious would not necessarily anticipate or render the other groups obvious.

Inventions VII, VIII, and IX are unrelated. It is noted that the invention of group VII is drawn to preventing or suppressing the expression of a mutation at the 552 codon and at the 526 or 528 codon in the DNA polymerase region of HBV in a host by administering a nucleoside. Groups VIII and IX are drawn to the same method, but they use divergent and patentably distinct compounds in their methods. Group VII uses nucleosides or compounds where X of formula I is O or S. Group VIII uses compounds which have SO_2 in the X position and group IX uses compounds which have CH_2 in the X position. As such, a search for a method of group VII would not be required for a search for the methods of groups VIII and IX, and a reference anticipating or rendering one group obvious would not necessarily anticipate or render the other groups obvious.

Groups I-III, are different than groups IV-VI. It is noted that groups I-III are drawn to methods of treating a host infected with a drug-resistant form of HBV by administering the various compounds. Groups IV-VI are drawn to methods of preventing or suppressing the expression of a mutation at the 552 codon in the DNA polymerase region of HBV. However, a reference anticipating or rendering one group obvious, would not necessarily anticipate or render the other groups obvious. A reference teaching method of treating an HBV infection may teach the active agent acts via a different route than by preventing or suppressing the expression of a mutation at the 552 codon.

Groups I-III are different than groups VII-IX. It is noted that groups I-III are drawn to methods of treating a host infected with a drug-resistant form of HBV by administering the various compounds. Groups VII-IX are drawn to methods of preventing or suppressing the expression of a mutation at the 552 codon and at the 526 or 528 codon in the DNA polymerase region of HBV. However, a reference anticipating or rendering one group obvious, would not necessarily anticipate or render the other groups obvious. A reference teaching method of treating an HBV infection may teach the active agent acts via a different route than by preventing or suppressing the expression of a mutation at the 552 codon and at the 526 or 528 codon.

Groups IV-VI are different than groups VII-IX. It is noted that groups IV-VI are drawn to methods of preventing or suppressing the expression of a mutation at the 552 codon in the DNA polymerase region of HBV. Groups VII-IX are drawn to methods of preventing or suppressing the expression of a mutation at the 552 codon and at the 526 or 528 codon in the DNA polymerase region of HBV. However, a reference anticipating or rendering one group obvious, would not necessarily anticipate or render the other groups obvious. A reference teaching method of preventing or suppressing the expression of a mutation at the 552 codon may not teach or fairly suggest methods of preventing or suppressing the expression of a mutation at the 552 codon and at the 526 or 528 codon using the same.

Groups I-IX and X-XVIII are related as methods of using the claimed compounds and methods of using the claimed compounds in combination or alternation with an effective amount of one or more other anti-HBV agents. It is noted that a reference anticipating or rendering obvious one of groups I-IX would not necessarily disclose or make obvious the use of a combination of agents, and additionally, any of the specific agents in claims 71 and 73. As such,

a search for one group would not necessarily be involved for the other, and a reference teaching or making obvious one group would not necessarily teach or render obvious the other.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

Claims 1-75 are generic to a plurality of disclosed patentably distinct species comprising a plethora of divergent compounds represented by the Markush group of formula I. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. By a single species it is meant a single compound. The compound may be named in any of four ways: 1) according to IUPAC standard, 2) by a pictorial representation of the compound, 3) by setting forth the specific chemical group that each variable of the Markush group represents, or 4) by naming a claim or an example which itself sets forth a single compound.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh
July 1, 2005

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623